Sept. 1, 1964 L. PERENY ETAL 3,146,884

STERILE SURGICAL DRAPE AND METHOD

Filed March 21, 1961 3 Sheets-Sheet 1

FIG-1

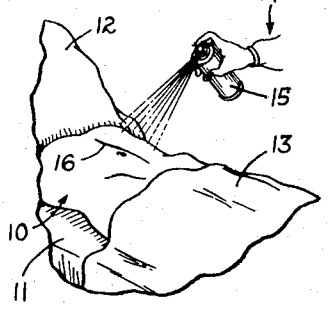

FIG-2

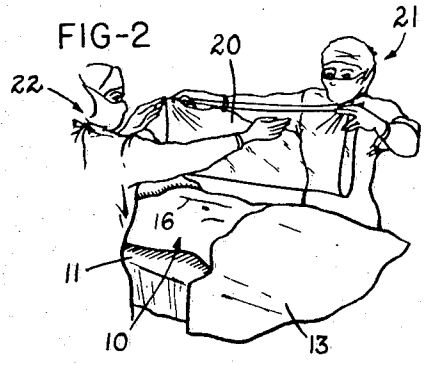

FIG-3

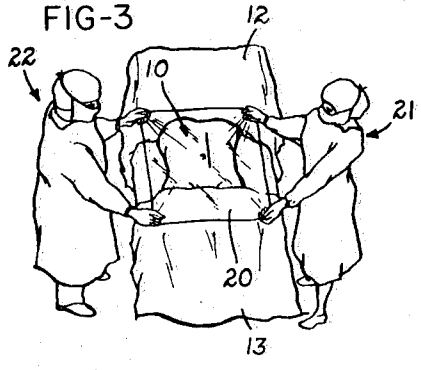

FIG-4

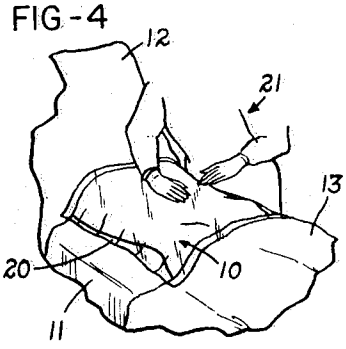

FIG-5

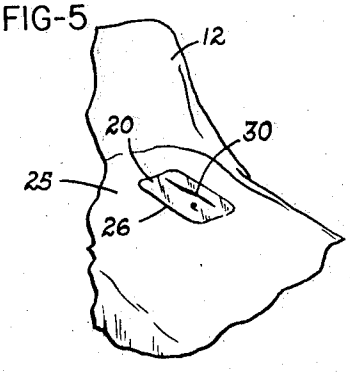

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FIG-6

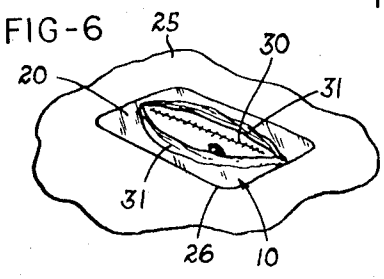


FIG-7

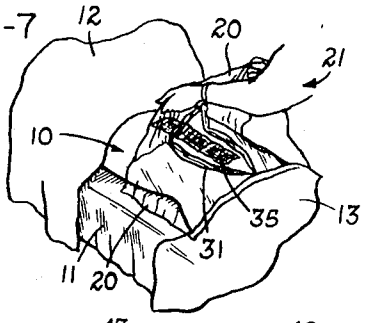


FIG-8

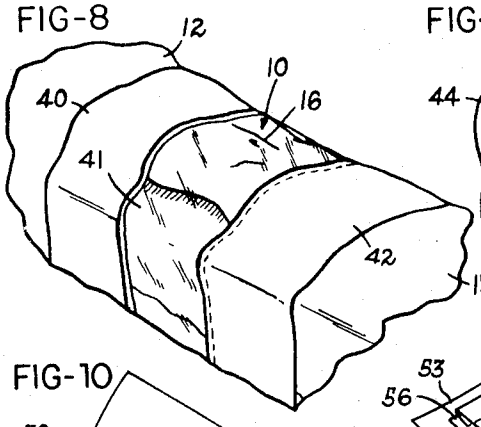


FIG-9

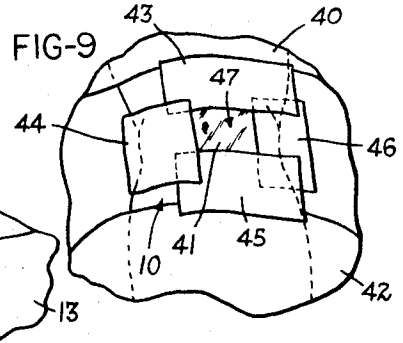


FIG-10

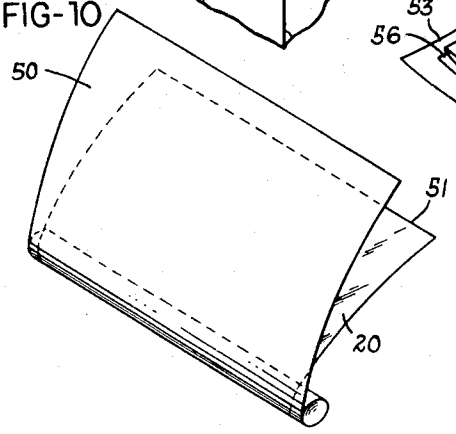
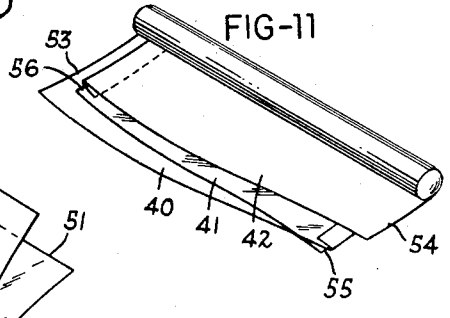


FIG-11



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STERILE SURGICAL DRAPE AND METHOD

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FIG-12

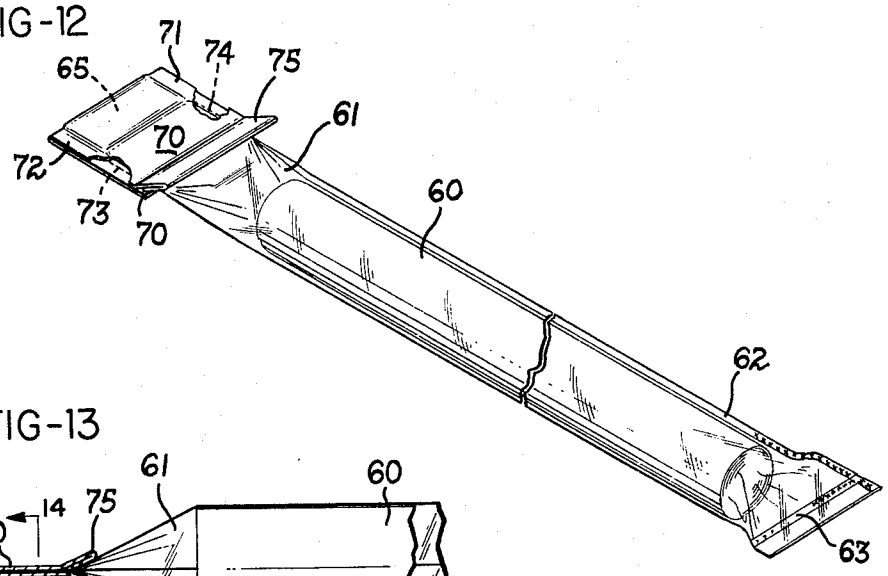


FIG-13

FIG-14

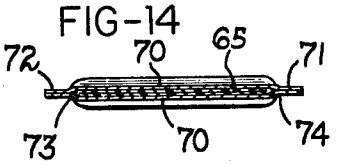


FIG-15

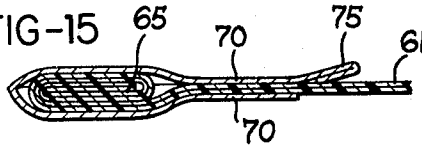


FIG-16

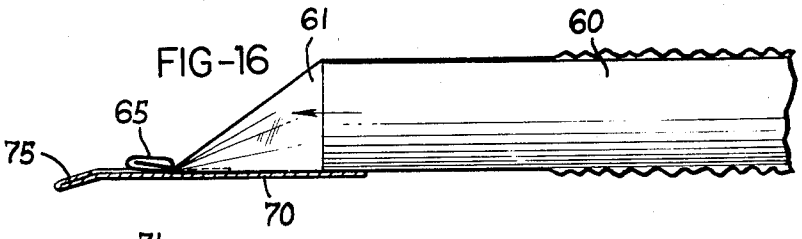
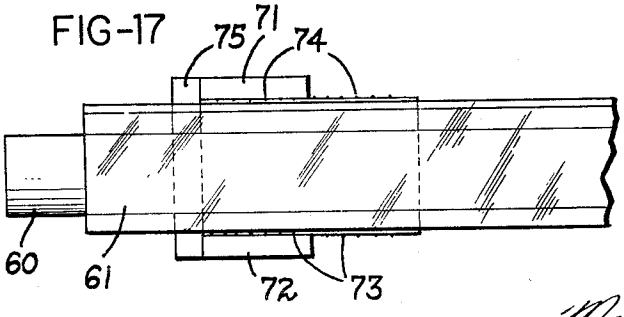


FIG-17



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3,146,884

STERILE SURGICAL DRAPE AND METHOD

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Filed Mar. 21, 1961, Ser. No. 97,333
7 Claims. (Cl. 206—63.2)

This invention relates to an improved surgical technique and, more particularly, to systems for accomplishing this new surgical technique with a sterile (or sterilizable) disposable, and, if desired, transparent drape or sheet material for covering a surgical patient in the operating room and to be adhesively held in place on the patient under sterile conditions to provide a sterile field in which the surgeon can operate. This application is a continuation-in-part of copending application Serial Number 45,262, filed July 21, 1960, and now Patent 3,060,932, issued October 30, 1962, as a continuation of the then-pending application Serial Number 756,670, filed August 22, 1958, and now abandoned.

It is considered by surgeons to be desirable, during a surgical operation, to have an operating field which is as completely as may be sterile, in the surgical sense, in which to function during the operation. Conventionally such surgically sterile field is prepared by "sterilizing" with antiseptic solutions and otherwise an area on the surgical patient's body adjacent the place at which the surgeon expects to make an incision and by surrounding this area with sterile towels or sheets, held in place by metal skin clips or occasionally by actually suturing the towel or sheet to the patient's body. Certain difficulties or disadvantages may arise with this conventional method of surgical preparation. For example, there may be a residuum of obnoxious bacteria left in or on the patient's skin even after the standard "sterilization" thereof. Similarly, the surgeon may desire or find it expedient to make a second incision in an area more or less remote or spaced from the originally designated area. Also, particularly with abdominal surgery, if a substantialy amount of blood or other body fluids are released from the incision or if certain organs are temporarily removed from the body cavity for later replacement, the tendency for cloth towels or sheets to absorb and retain blood or body fluids or the moist covering of body organs present conditions to the surgeon which, if not actually disadvantageous or dangerous, are at least undesirable. A further objection is the need to use skin clips with which to hold the towels or sheets in place. These not only interfere with the freedom of movement of the surgeon and his operating team, but often cause trauma at the points of attachment to the patient's body.

According to this invention, however, a drape or sheeting is provided from inexpensive and disposable plastic materials, paper, and the like, which may be readily and repeatedly sterilized by wet heat or otherwise, and can be applied by sterile personnel in the operating room directly to the skin of the surgical patient and adhered thereto with a sterile adhesive composition previously applied to the patient's skin so that, particularly in the area adjacent the intended incision, the drape or sheet material is continuously adhered to the patient's skin to form a surgically sterile field upon the patient with encapsulation or immobilization of any residual bacteria on the patient's skin adjacent the area of incision. This has the important advantage that the sterilized area of operation is maintained in complete surgical isolation from the surgeon and the surrounding operating theatre. As a further feature of this invention, the drape or sheet material is selected to be transparent in whole or in part and to include the quality or characteristic of being resistant to absorption and retaining of aqueous body fluids, and is

provided in a packaged form which promotes sterilization of the drape material, minimize harmful effects of high temperature heat sterilization of the drape material, and yet presents the drape material in a package which facilitates application of large sheets thereof readily to the patient by sterile personnel in the operating room without contamination of either side of the applied drape material.

One object of this invention is to provide a system and method for forming in surgical operations an extended sterile area of disposable, substantially non-absorbing drape material releasably adhered to the skin of the surgical patient, through which drape the surgeon can make one or more incisions without raising the drape and with the drape adhered to the patient releasably in a manner to encapsulate and/or immobilize residual bacteria on the patient's skin and prevent infection of an incision through the drape or the skin, and to completely isolate the patient surgically from the surgeon except at the line of incision.

Another object of this invention is to provide a packaging method for the protective packaging of a disposable surgical drape sheet material of the character described in a particular configuration facilitating heat sterilization of the material in its package and aseptic unpackaging thereof by sterile personnel in the operating room for application to a surgical patient and without contaminating the sterilized drape material.

A further object of this invention is to provide, in a system and method of the character described, a disposable and repeatedly sterilizable surgical drape for releasable adherence to the skin of a surgical patient and having the combined characteristics of cloth-like draping and silence, lack of absorption for aqueous body fluids, and receptivity to a previously applied adhesive for adhering the drape to the skin of the patient.

Still another object of this invention is to provide, in a system and method of the character described, a prepackaged non-woven synthetic surgical drape, a portion of which is transparent, and including a packaging technique to facilitate the heat or other sterilization of the material and the application of large sheets thereof by sterile personnel in a surgical operating room for releasably adhering the material to the skin of a surgical patient.

A still further object of this invention is to provide, for a system and method of the character described, a prepackaged and repeatedly sterilizable disposable surgical drape including a portion of paper sheeting and an additional portion of transparent synthetic plastic sheeting to be releasably adhered to the skin of a surgical patient for forming a sterile field thereover with transparent portions of the sheeting applied in a predetermined area adjacent a surgical incision to be made therethrough.

Still a further object of this invention is to provide an arrangement for packaging a synthetic surgical drape material of the character described whereby individual rolls or pieces of the drape material are included within an outer covering and may be permanently sterilized at the point of manufacture for later use as a sterile surgical drape by sterile operating personnel without contamination by the intermediate handling by non-sterile personnel.

Still another object of this invention is to provide arrangements for packaging rolls or pieces of surgical drape material of the character described in sealed outer coverings in such manner that the drape may be sterilized within the sealed covering, and with the covering so constructed that it may be opened and the drape material may asceptically be removed therefrom by sterile operating room personnel without having either the sterilized drape or the sterile personnel contaminated by the non-sterile condition of the outside of the covering or by non-

sterile personnel handling and holding the covered package.

Other objects and advantages of this invention will be apparent from the following description, the accompanying drawing, and the appended claims.

In the drawings:

FIGS. 1–7 inclusive, illustrate a satisfactory technique for practicing a method embodying this invention including a transparent drape material and an overlaid apertured paper or cloth operative drape;

FIG. 8 illustrates a modified form of drape embodying and for practicing this invention in which a central portion only of the drape is transparent;

FIG. 9 illustrates a further step of restricting or defining the transparent area of the drape of FIGS. 8 or 5 with overlaid non-transparent pieces of drape material;

FIG. 10 illustrates means for packaging the transparent plastic drape of FIG. 2 with a rolled and interleaved protective paper wrapping for the sterilization thereof;

FIG. 11 illustrates a means of packaging the drape of FIG. 8 for the sterilization thereof;

FIG. 12 illustrates a roll of drape material embodying and for practicing this invention enclosed within a sealed outer covering;

FIGS. 13–15 are partial sectional views illustrating in more detail the construction of the sealed closure of the package of FIG. 12 at an end thereof to be opened for asceptic removal of the drape contents, with FIG. 14 being a section on the line 14—14 of FIG. 13; and

FIGS. 16 and 17 illustrate two successive steps in opening the sealed end of FIGS. 13–15 for the asceptic removal of the drape contents from the package of FIG. 12.

Considering as particularly illustrative of a surgical technique to which this invention is applicable the area of abdominal surgery, it should be noted, as is well understood, that a sterile surface area should be, most desirably, presented to the surgeon. With conventional surgical techniques, an area of the skin is "sterilized" with various antiseptic compositions adjacent to the point at which the incision is intended to be made, and yet, as is well recognized among surgeons, such sterilization may, indeed, fail to remove completely from the skin all the bacteria or living organisms thereon, if only because of the non-planar configuration of the skin and the many interstices, pores, and follicles in which bacteria may proliferate or live regardless of the customary pre-operative scrubbing and swabbing or other treatment with antiseptic compositions.

Nevertheless, conventional practice indicates that a particular small area of incision is sterilized with antiseptic substances and then isolated by surrounding it with a plurality of sterile towels or sheets to provide a generally sterile or aseptic field for the surgeon while he is working. Whether or not the edges of such towels or sheets be adhered to the patient's skin to minimize the possibility of contamination of the incision with bacteria which might gain access thereto from other areas of the patient's skin beneath the edges of the surrounding towels, such techniques, however conventional, have a tendency to concentrate the surgeon's activity to the particular small skin area originally suggested, although there may be occasion for an unanticipated second incision to be made in an area remote from that originally selected. Similarly, the utilization of cloth towels or sheets, as is conventional, in many types of surgery, forms a messy residuum for the absorption of blood and other body fluids so that, as the operation progresses, the originally sterile area becomes less and less aseptic, and, in cases where various body organs are removed from the body cavity temporarily later to be replaced and where it is desired to keep these removed organs moist, the utilization of absorptive cloth towels and sheets to provide the desirable surgical field exhibits further undesired qualities.

Obviously, also, there is the well understood factor that all of the sterile field towels and sheets conventionally

used must be laundered, and this factor alone produces, particularly in hospitals with busy surgeries, a substantial extra expense. For example, in one metropolitan hospital the operating room laundry amounted to an average of approximately 22 tons per month—an important economic factor, to say nothing of the concomitant factor in, for example, Armed Services field hospitals, where adequate laundry facilities for sterile towels and drapes may simply be nonexistent.

By contrast, a disposable sheet or drape according to this invention can, with one piece unity, be releasably adhered over all the possible desired sterile area of the patient's body in a manner to assure not only complete isolation of the patient from the surgeon but also to provide an area free of blood or other surgical offal, which can be readily washed from the drape and not absorbed thereby, as well as encapsulating and immobilizing surface bacteria on the skin of the patient which may escape the pre-operative antiseptic treatment. Generally, especially where all or part of the drape is of a transparent material, an incision may be made at any point on the sterile field and through the transparent drape, almost completely without regard to whether such incision is in an area pre-operatively designated or in a widely varying area as may be required in, for example, such instances as where a patient, under abdominal surgery, collapses on the operating table and requires an emergency thoracic incision for access to the heart for manipulation by the surgeon.

As noted more particularly below, a drape or sheet embodying and for practicing this invention may be entirely made up of a lightweight transparent plastic sheeting, may comprise in part transparent sheeting and in part opaque plastic sheeting or paper sheet material, or may be composed initially entirely of opaque plastic or paper sheet material through which the surgeon or preoperative personnel cut windows or holes to be covered or closed by small pieces of transparent sheeting adhered to the patient's skin in the manner described. In any case, the paper or plastic sheet material is selected to be soft and flexible to have good draping effect, preferably stretchable so as to be readily molded for adherence over the contours of the patient's body and to include the property of shedding aqueous liquids. Considering paper sheet materials, this last mentioned characteristic suggests the desirability that a so-called wet strength paper of little absorptivity be used, not only for its ability to shed blood and body fluids from above but also to retard the tendency of the drape to absorb perspiration from the patient. That is, many surgical patients under anesthesia have a tendency to perspire freely, and absorption of this perspiration by any drape material in contact with the patient's skin is accompanied by a chilling effect which may not be desirable.

One important consideration in the selection and correlation of one or more sheet materials to be utilized in a drape embodying and for practicing this invention is the susceptibiiity of the material to withstand repeated heat sterilizing treatments. Thus, the various materials and towels, etc., utilized in operating rooms sterilized in steam autoclaves at temperature ranges of approximately 250° to 270° F. Normally, extra drapes are sterilized at each operation in case they should be needed, and any extra ones not used in one operation would, normally, be sterilized again for a subsequent operation. As will be understood, there are many plastic or paper sheet materials which become brittle or otherwise deteriorate when repeatedly subjected in the package to such sterilizing treatments.

As noted more particularly below, lightweight heat-stabilized transparent polyvinyl chloride sheet material is satisfactorily useful in accordance with this invention and will withstand repeated such heat sterilizing treatments. It is noted, however, that such plastic sheet materials may have a softening range beginning in the vicinity of

300° F., so it is preferred, in using such materials either for the entire drape or a part thereof, to arrange the package therefore as noted below in a manner so that there is interleaved between layers of plastic sheet material a layer of suitable paper or other suitable sheet material to prevent plastic-to-plastic contact during heat sterilization. The interleaved sheet should preferably be selected resulting from heat sterilization exposure. It is also contemplated that laminated sheet materials such as polyethlene-paper laminates, vinyl-paper laminates, etc., give satisfactory results and particularly in view of the paper side of the laminates being readily adhered to the patient while the plastic side of the laminate gives increased resistance to the penetration and absorption of aqueous body fluids.

Satisfactory results according to this invention are achieved using sterile sprayable synthetic plastic adhesive compositions particularly adapted to the surgical uses here involved for adhering the drape to the patient. Illustrative such compositions are disclosed in the copending application of Louis Pereny et al., Serial No. 756,512, filed August 22, 1958. As noted in said application, such a sprayable liquid dressing is applied to the skin of the patient to provide a continuous sterile adhesive film thereover, which film, even after solvent elimination, maintains a prolonged but limited tackiness so that drape or sheet material according to this invention may be positioned on the patient and will adhere to the adhesive film, although it may be readily removed and repositioned, in order to eliminate all air bubbles, etc. without disturbing the adhesive film or interfering with the final adherence of the drape material.

Satisfactorily, the drape material, whether all transparent plastic or all paper sheeting or combination of both, is supplied in a variety of sizes. For some types of surgery, the availability of a sterile and readily adherent sheet or drape of, approximately 48″ x 68″ gives satisfactory results enabling the surgeon to cover virtually all of the patient to form a sterile field, although the drape may be directly adhered to the patient's skin by continuous adhesive film in only the area adjacent the incision. For other types of surgery, smaller sizes may be packaged for specific applications. Thus, the use of a smaller size drape carefully applied may, in facial surgery, eliminate or minimize the inevitable possibility of contamination of the surgeon's gloves resulting from the patient's continued breathing. Similarly certain obstetrical manipulations during childbirth present a situation where contamination of the physician's gloves may occur from contact of this thumb with the anal region of the patient. Also, as noted below, it may be desired to have available smaller sterilized pieces of both transparent and paper sheet or drape material, either for forming transparent "windows" in an over-all paper drape or for forming an opaque outline of the area of surgical onslaught when using a transparent drape.

Referring to the drawing, in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1–7 indicate various steps in the utilization of a system and method embodying and for practicing this invention. Thus, FIG. 1 indicates a surgical patient **10** lying on a conventional operating table **11**, preparatory to the performance of, as illustrated, an abdominal surgical operation. The patient has previously received standard preoperative and sterilizing treatment and is indicated as being positioned with substantially the entire abdominal area exposed with conventional drape coverings **12** and **13** for nonoperative areas. A nurse or other operating room personnel, indicated at **14**, is shown applying an appropriate adhesive to the operative region as by an aerosol bomb or spray container **15**. According to conventional technique, a line of proposed incision **16** has been indicated on the patient's body as by a marking of iodine, or the like.

As indicated in FIG. 2 a sterilized drape sheet material **20**, in this case transparent, has been removed by sterile operating room nurses **21** and **22**, from a sterilized package thereof and in a manner described below, and for applying over the exposed portion of the patient's body **10** to which, as in FIG. 1, an appropriate adhesive composition has previously been applied. As indicated in FIG. 3, the transparent drape **20** is spread across and lowered onto the patient **10**, and then, as indicated in FIG. 4, smoothed and molded to conform to the exposed body portion of the patient **10** to adhere continuously and uniformly thereto, with the removal of air bubbles, etc., under the drape **20** and, if necessary, repeatedly raising and lowering and smoothing the drape **20** to form the desired operating surface or area.

Thereafter, if desired, a further opaque surgical drape **25** of paper or the like may be applied over drape **20** to isolate but a portion thereof as, for example, through an aperture **26** of any desired size cut therein, and the surgical incision **30** is made directly through the transparent drape **20** continuously adhered to the skin of the patient for encapsulation or otherwise immobilizing any residual bacteria or organisms on the skin of the patient and maintaining the area in sterile surgical isolation from the surgeon.

Thereafter the surgical operation is accomplished according to any desired technique, the transparent drape **20** being continuously adhere to the skin of the patient **10** not interfering in any manner with conventional surgery since, while it remains adhere to the skin of the patient right up to the lips of the incision, it is retracted, stretched, folded, etc., as may be necessary or desired, in the same manner as the epidermal layers or tissues are conventionally treated. Upon completion of the surgical operation, and approximately at the time when final suturing of the epidermal layers is to be accomplished, the edge portions **31** of transparent drap **20** are peeled back an inch or so from the lips of the incision **30**, and suturing of the latter proceeds in the conventional manner, as indicated in FIG. 6. Thereafter, as indicated in FIG. 7, the upper or opaque drape **25** is removed, conventional gauze pads **35** are applied for temporary absorption over the sutured incision **30**, and the transparent drape **20** is peeled away completely from patient **10** preparatory to final dressing of the operative wound according to conventional techniques. Any residual tackiness of the adhesive layer remaining on the exposed body portion of the patient **10** may be ignored as having no particular adhesiveness for bedclothes and the like not pressed firmly thereagainst as in FIG. 4, or may be neutralized effectively by dusting with cornstarch or talc (conventionally readily available in an operating room) or by spraying, along with the final dressing of the surgical wound, by a sprayable surgical dressing, such as is disclosed in Patent No. 2,804,073 to Gallienne et al. for later peelable removal, if desired.

As indicated in FIG. 8, a drape material embodying and for practicing this invention may desirably and satisfactorily be fabricated from a combined series of sheet materials including a paper or other opaque sheet material **40** having therein a transparent portion **41** to which is further adhered an opaque portion **42**. Such an arrangement is particularly adapted for abdominal operations wherein the entire drape, consisting of the two opaque paper or other sheet material portions **40** and **42** adhere to an intermediate portion **41**, may be applied and, if desired, only the transparent intermediate portion **41** adhered to the patient **10** with the disposable or other sheet material portions **40** and **42** arranged in conventional manner over nonoperative areas of the patient.

With such an arrangement, it may be convenient, as indicated in FIG. 9, for the surgeon to apply, with the aforementioned adhesive, or otherwise, extra pieces of opaque sheet material **43–46** to isolate, for a particular use an operative area **47** upon the transparent portion **41** of the drape. Such a convenience, perhaps conforming to conventional practice of isolating a small operative area, has, according to the present invention, the advantage that,

should the surgeon feel a second incision were necessary, he would merely have to remove or peel off any one of the overlying pieces 43–46 to reveal a perfectly sterile area, still beneath the transparent section 41, for such secondary incision and without the necessity of removing the conventional towels or cloth drape or without the necessity of worrying about preoperative sterilizing procedures since the entire area of the patient 10 to which either transparent portion 41 or opaque portions 40 and 42 is adhered may be considered as surgically sterile and, even more so, available for a completely sterile incision in view of the encapsulating function of the drape according to this invention and as adhered to the patient's skin by the releasable adhesive as disclosed.

As noted, the sheet material drape according to this invention preferably is packaged in a manner which is both suitable for heat or steam or other sterilization thereof and convenient for noncontaminating handling by sterile operating room personnel in use. If the drape is entirely of transparent plastic sheeting which might become slightly softened or tacky upon repeated sterilization thereof at conventional autoclave sterilizing temperatures, the plastic material is preferably interleaved with a paper or other sheet material liner to avoid the possibility of one layer of plastic sticking to another upon repeated sterilizations thereof.

Also, such interleaving paper liner materials are, preferably, of a highly permeable nature to allow substantially uninhibited penetration of steam, etc., in the autoclave for sterilizing purposes. Similarly, the drape material may be loosely rolled, rather than folded, to eliminate corners or folds or creases which might escape the sterilizing effect and harbor undesirable organisms and to promote axial penetration of the sterilizing steam between the layers of the roll.

It may be found, however, that the efficiency of sterilization is enhanced by assuring a substantial amount of humidity in direct contact with the drape being sterilized—i.e., a substantial amount of moisture plus heat, rather than just heat alone, may permit more effective sterilizing action at less drastic thermal conditions, which themselves may be desired with certain of the synthetic plastic sheet materials satisfactory for use in accordance herewith. Thus, especially with a fairly absorbent sheet material interleaved between adjacent convolutions of the rolled drape, making the roll of plastic sheet material and interleaved paper a fairly tight roll enhances the sterilization, efficiency, perhaps by increasing the wicking action of the interleaved paper in conducting the sterilizing atmosphere satisfactorily throughout the rolled material for adequate contact with all areas of the surfaces of the drape material being sterilized.

As indicated in FIG. 10, one suitable packaging system for a transparent plastic drape embodying and for practicing this invention comprises a relatively loosely rolled combination of transparent plastic drape or sheet material 20 interleaved or rolled within a disposable paper sheet material liner 50. As will be noted from FIG. 10, the width of paper liner 50 is somewhat greater than that of plastic sheet 20 so that there are no exposed edge portions of plastic sheet 20 in any part of the roll being sterilized. Similarly, the length of liner 50 is sufficiently greater than plastic sheet 20 so that, upon sterilization of the composite roll, there are no edge or other portions of plastic sheet 20 exposed to bacterial contamination. Since it is preferred to have the composite roll of liner 50 and transparent drape 20 rather loosely rolled for the axial penetration of sterilizing heat and steam between the various layers thereof, a loose paper or fabric outer wrapper (which may, indeed, be the conventional sterilizing towel) is preferably provided, and, as further protection, such wrapper may satisfactorily be of moisture-permeable cellophane, or the like, with the ends closed by pressure-sealing, heat-sealing, twisting, or other suitable manner to prevent entrance of contaminating dust or bacteria. In the absence of an outer wrapper such as cellophane, any paper outer wrapper is preferably of fairly pervious construction with the ends thereof tucked into the open ends of the roll. It may also be convenient to place on the outer wrapper a label or other indicator printed with an ink which changes color during heat or steam sterilization as, for example, that shown in the patent to Berman et al. No. 2,118,144.

After sterilization of the drape, one or more rolls thereof are made available in the operating room. The outer wrapper may be sterilly removed without contamination of the roll by cutting off the sealed ends, untwisting or removing the towel in known manner, and the drape 20 itself is removed, by a sterile nurse, as by grasping one edge 51 thereof and shaking vigorously to unroll the drape 20, allowing the liner 50 to drop on the floor, or by exposing one edge 51 of drape 20 on a sterile table and stripping the liner 50 therefrom. Thereafter, the transparent drape is handled as in FIGS. 2, etc., for application to the patient.

As indicated in FIG. 11, referring to a type of drape (noted in FIG. 8) as having a central transparent portion 41 and additional opaque paper or other sheet material and portions 40 and 42, satisfactory packaging thereof includes folding the composite drape so that, before rolling into a roll, paper portions 40 and 42 completely overlie the transparent portion 41 of the drape to prevent plastic-to-plastic contact in the roll to be sterilized. Additionally, it is preferred that the extreme edges 53 and 54 of portions 40 and 42 extend beyond edges 55 and 56 of transparent portion 41. One ready means of accomplishing this is to cement, at least temporarily, the edges of the various portions 40, 41 and 42, and then to fold the finished drape longitudinally with such cemented seams inside. It should be noted that even a temporary adhesive (actually, the same temporary adhesive as is used for adhering the drape to the patient) may be used and will form a permanent adhesive bond between plastic portion 41 and paper portions 40 and 42 under the effect of heat during the heat sterilization of the rolled drape as was intended with FIG. 10. The composite drape of FIG. 11 is loosely rolled, for ready penetration of sterilizing steam axially of the roll between the layers thereof, and is enclosed within an outer paper or cellophane or other wrapper for handling after sterilization to present the rolled drape in sterile and uncontaminated state to the sterile operating room personnel as above disclosed.

A further or preferred arrangement for the packaging of individual rolls of drape material is illustrated in FIGS. 12–17, which arrangement gives particularly satisfactory results when the sterilization of the drape material is to be accomplished by ethylene oxide, instead of by steam or heat, as by subjecting the rolls of drape material in an evacuated vessel to an atmosphere of ethylene oxide gas for sufficient time to destroy bacteria therein to acceptable levels, all in known manner. Indeed, such an arrangement may be preferred in the packaging of drape materials in accordance herewith since satisfactory results have been achieved and desirably permanent sterilization has been accomplished with ethylene oxide sterilization at the point of packaging of the drape materials to eliminate the need for additional sterilization immediately before use in the operating room, provided a sealed or other suitable outer covering for the drape material is arranged to prevent subsequent contamination thereof during handling and storage by nonsterile personnel.

Referring to FIGS. 12–17, one such satisfactory arrangement is illustrated. Thus, a roll 60 of plastic drape material interleaved with paper sheeting is indicated as enclosed within a sealed outer covering 61 of transparent plastic. In the illustrated embodiment, the roll 60 is formed somewhat as indicated in FIG. 10, but more tightly rolled, with the drape material being transparent poly-

vinyl chloride sheeting of a thickness within the range of about 0.001" to 0.005", and with the interleaved paper being sufficiently larger than the plastic drape material so that the paper, at the ends and edges of roll **60**, extends beyond the plastic sheeting in the manner indicated in FIG. 10. Covering **61** is preferably formed of highly impervious and waterproof plastic material such as polyethylene or nylon or polyvinyl film or sheeting, and may either be an extruded tube or a wrapper with a longitudinal seam **62** heat sealed together. Wrapper **61** is also permanently heat sealed at one end thereof as at **63**, and is preferably, as illustrated, substantially longer than roll **60**.

It is the end opposite to heat sealed end **63** which it is desired to be asceptically openable in the operating room for the sterile removal of roll **60** from covering **61**, and one satisfactory construction for accomplishing this purpose is illustrated in somewhat more detail in FIGS. 13–15. Thus, covering **61** is sufficiently longer (e.g., five or six inches) than roll **60** so that, after roll **60** is inserted within tubular covering **61**, the end of the tube opposite to heat sealed end **63** may be folded over on itself two or three times to form the multiple-layer fold indicated at **65**, while still leaving some length of covering **61** between the fold **65** and the end of roll **60**. A fabric or paper or other closure seal **70** is applied and adhered (as by pressure-sensitive adhesive which is not softened or affected by sterilizing) over and enclosing the folded end of covering **61**.

As will be noted, particularly from FIGS. 12–15, seal **70** is somewhat wider than the folded or flattened dimension of covering **61**, to provide edge seals at **71** and **72** where, as indicated in FIG. 14, two layers of seal **70** are adhered together completely enclosing the side edges of covering **61** and multiple folds **65**, and seal **70** is of sufficient continuous length to wrap completely around top and bottom surfaces of the folded end **65** of covering **61** and for a substantial axial extent therebeyond back toward roll **60**. Also scored or partially perforated or weakened tearing lines **73** and **74** may be provided along edge seals **71** and **72** to aid in tearing seal **70** open. Preferably, a loose or non-adhered opening tab **75** is provided one edge of seal **70** whereby, if one grasps tab **75** and strips it and seal **70** away from covering **61** toward the left in FIGS. 13 and 15, the center portion of seal **70** will be disengaged from itself (as by tearing along lines **73** and **74**) and from one surface of cover **61** to the condition illustrated in FIG. 16.

Thereafter, since multiple folds **65** of cover **61** are merely folded together, not adhered together other than by being enclosed within the folded seal **70**, roll **60** may be ejected from within covering **61** by pulling covering **61** back over roll **60** (as indicated by the wrinkles shown at the right-hand end of FIG. 16) whereby the end of roll **60** will itself cause the expanding and unfolding of the multiple folds **65** in cover **61** to progress from the situation illustrated in FIG. 16 to that illustrated in FIG. 17. Continued forcing of roll **60** out of covering **61** permits a sterile end thereof to protrude sufficiently, as in FIG. 17, to be grasped by a sterile operating room nurse without touching any contaminated part of the outside of cover **61**.

As will be apparent from the foregoing, the continuous adherence of seal **70** all around the surfaces and edges of the left end of covering **61** in FIGS. 12–15 assures the sterility or asceptic condition of all the surfaces of covering **61** enclosed within seal **70**, notwithstanding contamination of the outer or exposed surfaces of seal **70** or the outer surface of the exposed areas of cover **61**, and especially if the adhesive selected for seal **70** is applied so as to assure substantially continuous bonding under all areas of seal **70**.

Thus, both inside and outside surfaces of the multiple fold **65** of cover **61** are sterile until seal **70** is broken. Upon opening seal **70**, from the position shown in FIG. 15 to that shown in FIG. 16 (which opening can be accomplished by non-sterile personnel grasping only tab **75** without touching or contaminating even the outside of multiple fold **65**), a sterile passage is formed for the ejection or extrusion of roll **60** from within covering **61** and without the need for anyone (sterile or non-sterile) to touch the previously sealed surfaces. As roll **60** is gradually ejected from within covering **61**, it causes the expansion and unfolding of multiple fold **65** to the condition illustrated in FIG. 17.

The amount or axial extent of covering **61** utilized to make the several multiple folds **65** is specificially selected so that, when all the folds **65** are unfolded by ejecting roll **60** therethrough, covering **61** will extend substantially beyond the edge of tab **75** on seal **70** (as in FIG. 17) to form an egress passage for roll **60** which is sterile on all surfaces and edges thereof so that, as roll **60** emerges from the open end of covering **61** in the position in FIG. 17, all possible surfaces of covering **61** contacting or adjacent the emerging roll **60** will be sterile and not contaminated by or even adjacent to any part of the outside of covering **61** which was touched by non-sterile personnel in opening seal **70** or handling the sealed package shown in FIG. 12 or in ejecting roll **60** from covering **61**.

In this manner, both inside and outside surfaces of covering **61** and the end edge portion thereof for several inches back from the end thereof are sterile at the moment roll **60** emerges therethrough and notwithstanding how contaminated other outer surfaces of covering **60** or the outer surfaces of seal **70** may have become.

Thus, as noted, the rolls **60** of drape material may be placed within coverings **61** and sealed as indicated in FIG. 12, and then sterilized within the sealed coverings, which sterility is maintained satisfactory because of the construction shown whereby no part of any surface of covering **61** which contacts roll **60** even during the removal thereof is touched or contaminated by any non-sterile personnel in the handling or storage or opening of the package shown in FIG. 12. As noted above, such a packaging arrangement is particularly adapted with satisfactory results to the utilization of ethylene oxide sterilization, rather than steam sterilization.

The roll **60** of drape material is inserted (obviously, in a non-sterile condition) into covering **61**, the end thereof folded down for several inches to form the multiple fold **65**, and the seal **70** is adhered thereover completely to enclose all areas thereof. Then the package, as indicated in FIG. 12, is placed in the sterilizing vessel, which is evacuated to a high degree of vacuum (as much as minus 27" Hg), and an ethylene oxide sterilizing atmosphere is then admitted into the vessel at about 130° F. (preferably with steam to produce a wet atmosphere) for the necessary amount of time to destroy bacteria. The ethylene oxide atmosphere is then withdrawn, and the sterilizing vessel relieved to atmospheric pressure, all as well understood.

Whereas the material of covering **61** (such as the polyethylene or other film mentioned) is impervious to water and many other materials, it is sufficiently gas permeable, at least at such conditions of vacuum, temperature, or pressure, that the material within covering **61** is subjected to the sterilizing atmosphere of ethylene oxide, notwithstanding the continuous sealing of covering **61**, by permeation of the gases through the polyethylene covering. Although such materials may be permeable to gases at drastic pressure differentials, they are not sufficiently porous to admit the passage of air-borne bacteria—the smallest of which is generally considered to be of a size of at least 5 microns. Thus, even though air will diffuse back through covering **61** and into the sealed interior thereof after ethylene oxide sterilization, air-borne bacteria are denied entrance by the sealing arrangement noted. Although a polyethylene covering **61** sealed in the foregoing manner might substantially interfere with attempted steam sterilization of roll **60**, satisfactory re-

sults are achieved utilizing the sterilization technique of subjecting the entire arrangement to a pressurized atmosphere of ethylene oxide, and, should conventional steam sterilization also be desired, it is readily accomplished by merely opening seal **70** for the admission of steam into roll **60**.

Indeed, satisfactory results are achieved by completing the packaging for shipment of the drape material in accordance herewith prior to sterilization. That is, as may be desired, a dozen or so packages as illustrated in FIG. 12 and completely sealed and ready for sterilization may be placed in a box for later use and a plurality of such boxes placed in a sealed shipping carton prior to sterilization, with the entire carton placed into the sterilizing vessel. As is well understood with ethylene oxide sterilizing techniques, the sterilizing gaseous atmosphere will satisfactorily penetrate the shipping carton and the individual boxes, just as it does the plastic coverings **61** of the individual rolls **60**, to achieve a desired degree of sterilization, and under conditions where the paper boxes or corrugated shipping cartons are not damaged as would be the case with high pressure steam or heat sterilization in a steam autoclave.

Thus the plastic or plastic-paper drape hereof and for practicing the disclosed draping methods in surgical operations is satisfactorily rolled and completely packaged in individual sealed containers and boxed for shipment at the point of manufacture. The boxes are then satisfactorily sterilized to a surgically acceptable asceptic degree, and the boxes or the individual rolls may be conventionally handled by the non-sterile personnel without contamination of the drape material within the individual packages as illustrated in FIG. 12, and, without additional sterilization at the point of use, non-sterile personnel may open the covering **61**, as described, and eject therefrom the still-sterile roll **60** of drape material for presentation to the sterile operating room personnel without contamination of the sterile personnel or the drape material being ejected, after which the sterile personnel satisfactorily separate the transparent drape from interleaved paper sheeting and apply the drape to the patient as heretofore described.

While the methods and products and arrangements herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise methods and products and arrangements, and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

1. An interiorly sterile package containing a sterile surgical drape for use in the operating room, said package being in sealed condition for handling by non-sterile personnel without contaminating the contained sterile surgical drape comprising in combination, an interiorly sterile envelope of synthetic plastic material impermeable to transfer of contaminating bacteria therethrough, a sterile surgical drape within said package, at least one end of said envelope being folded upon itself in a plurality of folds and being sterilized on both the inside and outside thereof, said plurality of folds being spaced axially from said drape to provide an intermediate section of envelope between said folded end and said drape, said end in the unfolded condition thereof extending substantially beyond said contained sterile surgical drape and providing an integral protective extension free of contamination, an interiorly sterile sealing member overlying and enclosing said sterile folded end to isolate the same from outside contaminants in the sealed condition of said envelope, said sealing member being wider than the width of said folded end to provide sealed edge portions extending laterally thereof, means forming a seal between said sealing member and said envelope in said intermediate section, tab means provided along one edge of said sealing member for rupturing the sealed edge portions and said seal means thereby exposing said folded end, said folded end being unfolded by movement of said drape when advanced outwardly through said protective extension by pressure applied to the opposite end of said envelope, said protective extension surrounding said drape during advance of said drape therethrough and providing a sterile protective area between the exposed portion of said sterilized drape and any contaminated portions of said sealing member and envelope for delivery of said drape to the surgeon in fully maintained sterile condition.

2. A packaged drape as recited in claim 1 in which said drape material is polyvinyl sheeting rolled within said envelope which is polyethylene sheeting.

3. An interiorly sterile package containing a sterile surgical drape for use in the operating room, said package being in said sealed condition for handling by non-sterile personnel without contaminating the contained sterile surgical drape comprising in combination, an interiorly sterile envelope of synthetic plastic material permeable by a sterilizing medium but impermeable to subsequent transfer of contaminating bacteria therethrough, a sterile surgical drape within said package, at least one end of said envelope being folded upon itself in a plurality of folds and being sterilized on both the inside and outside thereof, said plurality of folds being spaced axially from said drape to provide an intermediate section of envelope between said folded end and said drape, said end in the unfolded condition thereof extending substantially beyond said contained sterile surgical drape and providing an integral protective extension free of contamination, an interiorly sterile sealing member overlying and enclosing said sterile folded end to isolate the same from outside contaminants in the sealed condition of said envelope, said sealing member being wider than the width of said folded end to provide sealed edge portions extending laterally thereof, seal means in said intermediate section adhered to said envelope, tab means positioned between said drape and said folded end and integral with said seal means for rupturing the seal means and said sealed edge portions when moved axially away from said drape, said folded end being unfolded by movement of said drape when advanced outwardly through said protective extension by pressure applied to the opposite end of said envelope, said protective extension surrounding said drape during advance of said drape therethrough and providing a sterile protective area between the exposed portion of said sterilized drape and any contaminated portions of said sealing member and envelope for delivery of said drape to the surgeon in fully maintained sterile condition.

4. A packaged sterile surgical drape material to be handled and opened by non-sterile personnel in a surgical operating room without contaminating the surgical drape contents of said package, comprising in combination a sterile surgical drape, an interiorly sterile sealed outer envelope containing said surgical drape and being substantially impermeable to contaminants deposited on the outside surface thereof during handling by non-sterile personnel, at least one end of said envelope being folded upon itself in a plurality of folds to provide a relatively flat end, said folds being sterile inside and outside and being spaced from said drape to provide an intermediate relatively flat section of envelope between said folded end and said drape, said folded flat end in unfolded condition thereof extending substantially beyond the surgical drape and providing an integral sterile protective extension free of contamination, a sealing member overlying and enclosing said sterile folded flat end, said sealing member including a continuous covering adhered to one surface of said intermediate flat section and folded over said folded flat end and sealed to the other surface of said intermediate flat section, said continuous covering being wider than the multi-folded end to provide edge portions extending laterally therefrom, said edge portions being sealed to each other, and tab means cooperating with said

continuous covering for separating the seals along the edge portions and for separating the covering in the area of said intermediate flat section, said folded end being unfolded by movement of said drape when advanced outwardly through said protective extension by pressure applied to the opposite end of said envelope, said protective extension surrounding said drape during advance of said drape therethrough and providing a sterile protective area between the exposed portion of said sterile drape and any contaminated portions of said sealing member and envelope for delivery of said drape to the surgeon in fully maintained sterile condition.

5. A packaged sterile surgical drape material to be handled and opened by non-sterilized personnel in the surgical operating room without contaminating the surgical contents of said package, comprising in combination a sterile surgical drape, a sealed outer envelope containing said surgical drape and substantially impermeable to contaminants deposited on the outside surface thereof during handling by non-sterilized personnel, at least one end of said envelope being folded upon itself in a plurality of folds to provide a relatively flat multi-folded end, said flat folded end being sterile and being spaced axially of the drape within said envelope to provide an intermediate relatively flat section of envelope between said flat folded end and said drape, a sealing member overlying and enclosing said folded flat end, said sealing member including a continuous covering adhered to one side of said intermediate relatively flat section and folded over said folded flat end and sealed to the other surface of said intermediate flat section, said continuous covering including portions extending laterally from said folded flat end and said intermediate section and being sealed together to form edge seals, tab means cooperating with said continuous covering for separating said edge seals and the seal between said covering and said other surface of said intermediate flat section, and said folded-end in the unfolded condition extending substantially beyond said tab means in an axial direction for allowing removal of said drape without contacting said sealing member and said tab.

6. A packaged drape material as recited in claim 5 in which said drape is rolled with an interleaved paper sheet into a roll within said envelope.

7. A packaged drape material as recited in claim 5 in which said envelope therefor is polyethylene sheeting.

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